



Nitta Casings Inc.

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November 7, 2005

Division of Dockets Management
Food and Drug Administration (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2004N-0081; Use of Materials Derived From Cattle in Human Food and Cosmetics

Dear Sir/Madam:

Nitta Casings Inc. (NCI) is hereby submitting the following comments on the Food and Drug Administration's (FDA) amendments to the second interim final rule on the use of materials derived from cattle in human food and cosmetics published on September 7, 2004. 70 Fed. Reg. 53063.

As mentioned in its original comments to the agency¹, NCI manufactures collagen casings at its facility in Somerville, New Jersey. NCI's collagen casings are manufactured from bovine hide collagen, all of which is obtained from hides of cattle slaughtered at federally inspected establishments.

NCI agrees with and commends the FDA for its clarification in the second interim final rule that hide and hide-derived products are not considered to be a "prohibited cattle material." NCI further agrees with the FDA that this amended provision will not jeopardize the level of protection from human exposure to the agent that causes bovine spongiform encephalopathy (BSE) as that provided under the initial interim final rule. 69 Fed. Reg. 42256 (July 14, 2004).

Declaring hide and hide-products as materials not to be identified as "prohibited cattle material" is justified due to cattle hides and bovine skin collagen being internationally recognized as safe commodities. The Office International des Epizooties (OIE) declares that bovine skin collagen is a safe commodity even if sourced from an animal with clinical BSE and accordingly recommends no BSE-related restrictions on trade in collagen from hides and skins, regardless of the BSE status of the country of origin.²

¹ The original comments by NCI to the FDA concerning Docket No. 2004N-0081 were submitted by the law firm Olson, Frank and Weeda, P.C. on behalf of the company.

² "When authorizing import or transit of the following commodities, Veterinary Administrations should not require any BSE-related conditions, regardless of the BSE status of the cattle population of the exporting country or zone:.... d. gelatin and collagen prepared exclusively from hides and skins." OIE, *Terrestrial Animal Health Code 2005*, Article 2.3.13.1.

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The OIE recently re-affirmed its position on the safety of bovine skin collagen during its April 2005 Meeting of the Permanent Commission of the Americas on Transmissible Spongiform Encephalopathies, again stating that importing countries should not require any BSE-related conditions for products derived from hides and skins of bovine animals.³

The Scientific Steering Committee of the European Commission has also concluded that collagen is safe for human consumption, provided only that it is sourced from hides that have passed ante-mortem inspection and the risk of SRM contamination is minimal. According to its report, cattle hides "are not considered to be part of the group of tissues that potentially represent a risk with regard to TSEs [transmissible spongiform encephalopathies]."⁴

As mentioned in its original comments to the agency, NCI only uses those hides that have received and passed ante-mortem inspection by federal inspectors to produce edible collagen casing. Therefore, NCI believes that the risk of SRM contamination of hides is negligible.⁵

NCI recognizes, as FDA has stated, that despite this clarification, the company must avoid the cross contamination of hides with other prohibited cattle materials during slaughter and processing. Any hides material that does not meet this requirement will be considered adulterated and not processed, as required by the agency.

³ OIE, Terrestrial Animal Health Code 2005, Article 2.3.13.1.

⁴ European Commission, *Opinion and Report on Safety with Respect to TSE Risks of collagen Produced from Ruminant Hides*. See also EC, *Updated Opinion on the Safety with Regard to TSE Risks of Gelatine Derived from Ruminant Bones or Hides from Cattle, Sheep or Goats* (reaching the same conclusion regarding gelatin made from cattle hides).

⁵ The only possible exposure of the hide to SRMs would result from brain splatter during stunning, which occurs prior to slaughter and hide removal. However, the Food Safety and Inspection Service (FSIS) condemns heads of cattle 30 months or older unless an establishment can ensure that stunning does not result in brain leakage. FSIS Notice 4-04 (Jan. 14, 2004). Even if an establishment cannot ensure that brain tissue does not leak onto the hide, any brain material adhering to the hide would be minimal and would be present only on the outer layer of the hide. Such brain matter likely would be removed from the hide in the raceway water or during subsequent washing and de-hairing of the hide at the tannery. In addition, since any brain matter would only be present on the outer layer of the hide, and that outer layer is stripped away and used for leather production, it would not contaminate the corium, the inner layer of the hide, which is used in the production of collagen casing. Finally, any brain matter likely would be present only on the faceplate, which is removed from the rest of the hide before the corium is stripped away. It is noteworthy that the OIE *Terrestrial Animal Health Code* does not exclude hide removed from the faceplate as material that should be traded without any BSE-related conditions.

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NCI again commends the FDA for agreeing with its initial comments and putting in place regulatory policies that reflect those of the OIE.

We appreciate the opportunity to provide comment to the agency.

Respectfully submitted,



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Senior Regulatory Affairs Associate
Nitta Casings Inc.